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| 2292 | 7590 | 10/30/2009 | EXAMINER | |
| BIRCH STEWART KOLASCH & BIRCH PO BOX 747 FALLS CHURCH, VA 22040-0747 | | | | GUGLIOTTA, NICOLE T |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

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mailroom@bskb.com

| | | |
|------------------------------|------------------------|---------------------|
| Office Action Summary | Application No. | Applicant(s) |
| | 10/594,918 | ABE ET AL. |
| | Examiner | Art Unit |
| | NICOLE T. GUGLIOTTA | 1794 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 23 June 2009.
 2a) This action is **FINAL**. 2b) This action is non-final.
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 2, 4, 8 - 10, 12 - 15, 28 - 30 is/are pending in the application.
 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
 5) Claim(s) _____ is/are allowed.
 6) Claim(s) 2, 4, 8 - 10, 12 - 15, 28 - 30 is/are rejected.
 7) Claim(s) _____ is/are objected to.
 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ . |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____. | 6) <input type="checkbox"/> Other: _____ . |

DETAILED ACTION

Examiner's Note

Examiner acknowledges the amendment to claim 2, the cancellation of claims 1, 3, 5 – 7, 11 &16 - 27, and the addition of claims 29 - 30. Claims 2, 4, 8 - 10, 12 – 15 & 28 - 30 are currently pending. The cancellation of claims 5 and 27 renders the previous rejection under 35 U.S.C. §112,first paragraph moot. Therefore, the rejection is withdrawn.

Considering claim 2, the “vinyl” group of the monomers is used for the polymerization process. Thus, when the process of polymerization is complete, resulting in the final polymer product bonded to the surface of the DLC, the "vinyl" (alkene or C=C) group of each monomer has been converted to a single carbon-to-carbon bond. A “polymer of vinyl monomers” does not contain a vinyl group, but simply indicates the mechanism for the polymerization process. Covalent bonds formed between monomers during polymerization or for the general bonding of one atom to another can be formed via numerous methods, not just from the chemical reaction of a vinyl group of a molecule. Therefore, the limitation of "polymers of vinyl monomers, vinylidene monomers, vinylene monomers, or cyclic vinylene monomers" makes claim 2 a product-by-process claim.

Claim 2 defines the product by how the product was made. Thus, claim 2 is a product-by-process claim. For purposes of examination, product-by-process claims are not limited to the manipulation of the recited steps, only the structure implied by the

steps. See MPEP 2113. In the present case, the recited steps imply a structure having a biocomponent covalently attached to the DLC surface. The reference suggests such a product.

Examiner refers applicant to MPEP § 2113 [R - 1] regarding product-by-process claims. "The patentability of a product does not depend on its method or production. If the product in the product-by-process claim is the same as or obvious from a product or the prior art, the claim is unpatentable even though the prior product was made by a different process." *In re Thorpe*, 777, F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) (citation omitted)

Once the examiner provides a rationale tending to show that the claimed product appears to be same or similar to that of the prior art, although produced by a different process, the burden shifts to the applicant to come forward with evidence establishing an unobvious difference between the claimed product and the prior art product. *In re Marosi*, 710 F.2d 798, 802, 218, USPQ 289, 292 (Fed. Cir. 1983)

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent

1. Claims 2, 8, 12 – 15 & 30 are rejected under 35 U.S.C. 102(a) as being anticipated by Lasseter et al. (J. Am. Chem. Soc. 2004, 126, 10220 – 10221).

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In regard to claims 2, 13, 14 & 30, Lasseter et al. disclose a medical material, used for implants and biosensors, comprising: a gold or silica substrate surface (corresponds to Applicant's "base material"), a diamond-like carbon biocompatible coating (corresponds to Applicant's "diamond-like carbon film"), and ethylene glycol oligomers (corresponds to Applicant's "biocompatible component: vinyl monomers"). The vinyl groups of the oligomers are covalently bonded to the diamond via a photochemical reaction with the hydrogen-terminated surfaces of the diamond coating (Pg 10220, left column, first paragraph & Figure 1).

In regard to claim 8, ethylene glycol, discussed above, contains a hydroxy group.

In regard to claim 12, the gold substrate, discussed above, is a metal material, and silica is a ceramic.

In regard to claim 15, Lasseter et al. disclose implants. An artificial joint is one particular type of implant (Pg 10220, left column, first paragraph).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. Claims 2, 4, 8, and 12 – 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Woo et al. (U.S. Patent No. 6,761,736 B1), as evidenced by Hamers et al. (Langmuir 2002, 18, 968 - 971).

In regard to claims 2 and 4, Woo et al. disclose “biocompatible material in addition to the diamond-like carbon coated polymer substrate...within the same component as the diamond-like carbon coated polymer material or in separate components” (Col. 6, Line 67 - Col. 7, Line 6). The DLC is formed on a polymer substrate (corresponds to applicant’s “base material”) (Col. 2, Lines 48 – 51). Such biocompatible components include vinyl polymers (e.g. polytetrafluoroethylene) (Col. 7, Lines 60 – 67). Woo et al. are silent in regard to whether the biocomponent is directly applied on top of the DLC via a covalent bond. Hamers et al., however, disclose it is known for a hydrogen-free diamond surface “to react with unsaturated C = C bonds of organic alkenes” (Pg 968, left column, second paragraph). Vinyl polymers, such as polytetrafluoroethylene, are organic alkenes containing unsaturated C = C bonds. Therefore, it would be reasonable to believe the addition polytetrafluoroethylene layer disclosed by Woo et al. covalently bonds to the diamond-like carbon (DLC) surface.

In regard to claim 8, Woo et al. disclose polysulfones are also an appropriate biocompatible material (Col. 8, Line 1).

In regard to claim 12, Woo et al. disclose the diamond-like carbon coating can be applied to a sawing cuff formed from a polymer fabric (corresponds to Applicant’s “macromolecular material”) (Col. 6, Lines 31 – 32).

In regard to claim 13 - 15, Woo et al. disclose the polymer substrate containing a DLC film and a biocompatible material are used for medical article that contact a patient's bodily fluids (Col. 2, Lines 48 – 51). Medical articles include catheters and prostheses (Col. 1, Lines 5 – 21).

3. Claims 2, 4, 12 – 15, 23 - 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Steffen et al. (*Surf. Interface Anal.* 29, 386 – 391 (2000); submitted by applicant), in view of Palmaz et al. (U.S. Patent No. 6,537,310 B1), as evidenced by Hamers et al. (*Langmuir* 2002, 18, 968 - 971).

In regard to claims 2, 4, 12, 29 – 30, Steffen et al. disclose a diamond-like carbon (DLC) film system that consists of a chemically inert, uniform, dense and highly tetrahedrally bonded, hydrogenated amorphous carbon film (ta-C:H) with high adherence to the substrate and bioactive heparin macromolecules that are covalently bonded to the ta-C:H film surface (Figure 1 & Page 387, 2nd Col., 2nd paragraph). Steffen et al. disclose the substrate materials (base materials) may include Si(100) wafers (Page 388, Col. 1, first paragraph of the experimental section). However, Steffen et al. do not disclose the biocompatible layer to contain silicon or vinylmonomers containing fluorine.

Palmaz et al. disclose

numerous attempts to increase endothelialization of implanted stents, including imparting a diamond-like carbon coating onto the stent (U.S. Pat. No. 5,725,573), coating the stent, under ultrasonic conditions, with a synthetic or biological, active or inactive agent, such as heparin, endothelium derived growth factor, vascular growth factors, silicone, polyurethane, or polytetrafluoroethylene (U.S. Pat. No. 5,891,507), coating a stent with a silane compound with vinyl functionality, then forming a graft polymer by polymerization with the vinyl groups of the silane compound (U.S. Patent No.

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5,782,908), *grafting monomers, oligomers or polymers onto the surface of the stent using infrared radiation, microwave radiation or high voltage polymerization to impart the property of the monomer, oligomer or polymer to the stent* (U.S. Pat. No. 5,932,299) (Col. 6, Lines 29 - 54).

It would have been obvious to one of ordinary skill in the art at the time of the invention to graft biocompatible layers containing vinylfluoride monomer molecules (polytetrafluoroethylene), in place of the heparin disclosed by Steffen et al., because such components and methods have been previously taught for increasing endothelialization and antithrombogenicity, as disclosed by Palmaz et al. Hamers et al., disclose it is known for a hydrogen-free diamond surface “to react with unsaturated C = C bonds of organic alkenes” (Pg 968, left column, second paragraph). Vinyl polymers, such as polytetrafluoroethylene, are organic alkenes containing unsaturated C = C bonds. Therefore, it would be reasonable to believe the addition polytetrafluoroethylene layer disclosed by Palmaz et al., as a substitute for the heparin disclosed by Steffen et al., covalently bonds to the diamond-like carbon (DLC) surface.

In regard to claims 13, 14, and 15, Steffen et al. disclose the film composed of DLC and surface-immobilized bioactive molecules optimize hemocompatibility for artificial implants of the cardiovascular system (Abstract and Page 386, Col.1, paragraph 1). In addition, the use of DLC films on polymers give rise to a universal application of these carbon materials for medical devices, such as total joint replacements, heart valves, catheters, stents, intravascular insertion devices and more (Page 388, Col. 1, first paragraph).

Claim 29 defines the product by how the product was made (i.e. via a hydroxy group (which will be converted to a vinyl group according to Applicant’s specification

paragraph [0060])). Thus, claim 29 is a product-by-process claim. For purposes of examination, product-by-process claims are not limited to the manipulation of the recited steps, only the structure implied by the steps. See MPEP 2113. In the present case, the recited steps imply a structure having a biocomponent covalently attached to the DLC surface. The reference suggests such a product.

Examiner refers applicant to MPEP § 2113 [R - 1] regarding product-by-process claims. "The patentability of a product does not depend on its method or production. If the product in the product-by-process claim is the same as or obvious from a product or the prior art, the claim is unpatentable even though the prior product was made by a different process." *In re Thorpe*, 777, F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) (citation omitted)

Once the examiner provides a rationale tending to show that the claimed product appears to be same or similar to that of the prior art, although produced by a different process, the burden shifts to the applicant to come forward with evidence establishing an unobvious difference between the claimed product and the prior art product. *In re Marosi*, 710 F.2d 798, 802, 218, USPQ 289, 292 (Fed. Cir. 1983)

In regard to claim 29, in addition to the hydrogen-free diamond surface, Hamers et al. disclose hydrogen-terminated diamond also react with layers of functionalized alkenes (such as vinyl polymers) to form covalent bonds (Pg 968, right column, second paragraph), as well as diamond surfaces containing carboxylic acid groups (Pg 971, right column, last paragraph). Carboxylic acids contain a hydroxy group.

4. Claims 9 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Steffen et al. and Palmaz et al., as evidenced by Hamers et al., as applied to claim 2 above, and further in view of Lemelson et al. (U.S. Patent No. 6,083,570).

Steffen et al. disclose a biocompatible layer attached to a diamond-like carbon (DLC) layer, which is applied to a substrate (base material). However, Steffen et al. do not disclose the use of an intermediate film between the DLC and the substrate (base material).

Lemelson et al. disclose articles with synthetic diamond or diamond-like carbon coatings with an intermediate amorphous metal bonding later. The residual stress in diamond and diamond-like thin film coatings applied to metal, cermet and ceramic substrates can be reduced to acceptably low levels by using an intermediate film coating of amorphous ("glassy") metal (Column 3, Lines 54 - 65). Such articles include dental tools and medical prostheses or implants intended for long-term use inside the human body (Column 4, Lines 4 – 11). The intermediate layer may be comprised of carbides or silicon. SiC is most preferred (Column 4, Lines 33 - 38).

It would have been obvious to one of ordinary skill in the art at the time of the invention that the addition of an intermediate SiC layer between the DLC and substrate in the disclosure of Steffen et al. would help to reduce the residual stress in diamond-like carbon thin film coatings used for medical applications. An organosilicon intermediate layer for increased adherence between a substrate and a DLC is also disclosed by Kato et al. (U.S. 5,763,072).

5. Claims 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Steffen et al. and Palmaz et al., as evidenced by Hamers et al., and further in view of Suto et al. (J. Bio. Chem. No. 280, No. 3, pp. 2126 - 2131).

Steffen et al. teach heparin ionically bonded to a DLC layer (heparin being negatively charged). Palmaz et al. disclose, as discussed for claim 2, coating the stent with heparin or other biomolecules, such as endothelium derived growth factors or vascular growth factors (proteins), in order to increase endothelialization of implanted stents. However, Palmaz et al. is silent in regard to how the vascular growth factors are bonded to the surface of the stint. Suto et al. disclose vascular endothelial growth factor-A (VEGF-A) is mostly negatively charged (pg 2130, 1st column), due to negatively charged amino acid residues containing carboxyl groups, such as aspartate (D63) and glutamate (E64) (Figure 2). As discussed for claim 2 above, it would have been obvious to one of ordinary skill in the art at the time of the invention that a biocompatible component, such as PTFE or vascular growth factors may be substituted for the heparin of Steffen et al. (disclosed by Palmaz et al.), because the biocompatible components have been shown to increase endothelialization of implanted stents. Suto et al. teach vascular endothelial growth factor-A is negatively charged due to negatively charged amino acids at its surface. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention that a negatively charged vascular growth protein disclosed by Palmaz et al. would bind to the DLC layer in the same manner (an ionic bond) as the negatively charged heparin disclosed by Steffen et al.

6. Claims 8 & 28 is rejected under 35 U.S.C. 103(a) as being unpatentable over Steffen et al. and Palmaz et al., as evidenced by Hamers et al., as applied to claim 2 above, and further in view of Han et al. (U.S. Patent No. 6,268, 161 B1).

In regard to claim 28, Steffen et al. and Palmaz et al. disclose biocompatible components, such as vinyl polymers, for coating medical devices. However, they are silent in regard to the specific use of 2-hydroxypropyl methacryl amide (HPMA). Han et al. disclose HPMA is a tough, flexible polymer that is highly biocompatible; as well as inert and nondegradable *in vivo*, a preferred trait for biosensors that are to be implanted into the human body (Col. 8, Lines 8 – 16). HMPA contains a hydroxy group. It would have been obvious to one of ordinary skill in the art at the time of the invention to use HPMA in the invention of Palmaz et al. as a preferred vinyl polymer because HPMA is inert and nondegradable *in vivo*.

Response to Arguments

7. Applicant argues, "...Examiner states that claim 2 is a product-by-process claim, and that the graft polymerization will not result in a different structure than suggested by the cited references of Steffen et al., Palmaz '310 and Lemelson '570 (see Office Action at paragraphs 44 - 46). However, Applicants note the changes to claim 2 as shown herein. Reconsideration respectfully requested in view of the changes to claim 2 wherein the biocompatible component is covalent bonded to the DLC film" (Remarks, Pg 10).

EXAMINER'S RESPONSE: Applicant's amendment removes the limitation of graft polymerization. However, Examiner maintains claim 2 is a product-by-process claim due to Applicant's limitation of "polymer of vinyl monomers". The "vinyl" portion of the monomers is necessary for the process of forming the polymers. Therefore, the "vinyl" (alkene) group of the monomers (the C = C) no longer exists when the monomers are in the form of a polymer. Therefore, the limitation of "vinyl monomers, vinylidene monomers, vinylene monomers, or cyclic vinylene monomers" makes the claim a product-by-process claim.

8. Applicant argues, "Woo '736 describes a medical device which has a part covered with a DLC film and another part covered with a biocompatible material. This structure is quite different from the medical material of claim 2 which includes the polymer (biocompatible component) covalently bonded to a DLC film that is formed on a base material" (Remarks, Pg 10).
9. Applicant argues, "Palmaz '310 fail to teach or suggest covalently bonding a polymer to a DLC film formed on a surface of a medical device" (Remarks, Pg 11).
10. Applicant argues, "...the citation of the secondary reference of Suto et al. does not make the rejection of claim 8 (in view of Steffen et al., Palmaz '310 and Suto et al.) any more proper" (Remarks, Pg 12).

EXAMINER'S RESPONSE: Applicant's arguments with respect to claim 2 have been considered but are moot in view of the new ground(s) of rejection.

11. Applicant argues, "Also, Woo '736 fails to teach or suggest bonding a polymerization starting end of a biocompatible component bound to the polymerization starting point on the surface of a DLC film" (Remarks, pgs 10 – 11).

EXAMINER'S RESPONSE: Applicant's arguments have been fully considered but they are not persuasive. First of all, in response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., polymerization starting points and starting ends) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Second of all, even if the claims recited a limitation of "bonding a polymerization starting end of a biocompatible component bound to the polymerization starting point on the surface a DLC film", Examiner would consider such a limitation to be product-by-process, based upon the final structure of Applicant's invention and the prior art cited above.

12. Applicant argues, "...since the method described in Steffen et al. uses NaBH₃CN, its method is only applicable to molecules having reducing ends, such as sugars. In other words, when the Steffen et al. method is used, a polymer which does not have a reducing end cannot be immobilized. Therefore, Steffen et al. is quite different from the structure recited in pending claim 2 where the biocompatible component which is a polymer of vinyl monomers, etc., is covalently bonded to the DLC film" (Remarks, Pg 11).

EXAMINER'S RESPONSE: Applicant's arguments have been fully considered but they are not persuasive. First, Examiner notes claim 2 is not a method claim. Examiner has not suggested the method Steffen et al. be used to substitute the polymers of vinyl monomers to the DLC film. It would have been obvious to one of ordinary skill in the art at the time of the invention that different biocompatible components require different methods due to differences in molecular structure. Thus the appropriate method should be used, according to the biocompatible component of choice. Second, Applicant's argument is moot in view of the teachings of Hamers et al.

13. Applicant argues, "The rejection of Baselt '297 is rendered moot with the cancellation of the disputed claims" (Remarks, Pg 12).

EXAMINER'S RESPONSE: Applicant's arguments with respect to the rejection(s) of claim(s) 24 - 25 under 35 U.S.C. §103(a) have been fully considered and are persuasive. Therefore, the rejection has been withdrawn.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to NICOLE T. GUGLIOTTA whose telephone number is (571)270-1552. The examiner can normally be reached on M - F 8:30 a.m. - 6 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David R. Sample can be reached on 571-272-1376. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see <http://pair-direct.uspto.gov>.

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/David R. Sample/
Supervisory Patent Examiner, Art Unit 1794

/NICOLE T GUGLIOTTA/
Examiner, Art Unit 1794